

## **EXHIBIT B**



Office of the Chief Counsel  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

July 9, 2019

**Via Email**

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Kevin M. Downey  
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Re: Document Request – *United States v. Elizabeth Holmes & Ramesh Balwani*, 18-CR-00258 EJD (N.D. Cal.)

Dear Messrs. Bostic, Coopersmith, and Downey:

Pursuant to the June 28, 2019 Order in the above-captioned action directing the United States Food and Drug Administration (“FDA”) to provide the parties with specific information regarding the documents it agrees to produce or objects to producing in response to the document requests made by the Government on behalf of Defendants, FDA replies as follows.

FDA is, and has been, working diligently to collect, process, review, and ultimately produce all documents responsive to all six categories requested by the parties. FDA’s collection and review began in response to an earlier subpoena by Defendant Balwani’s counsel, Mr. Coopersmith, in the separate but related matter *Securities and Exchange Commission v. Ramesh “Sunny” Balwani*, Civil Action No. 5:18-cv-01603 (N.D. Cal.) (the “SEC matter”). That subpoena requests, among other items, “all documents and communications referring or relating to Theranos, Holmes, or Balwani” (Balwani SEC RFP No. 1). Because all six categories of documents requested in the above-captioned matter are subsumed by the subpoena issued in the SEC matter, FDA has effectively been collecting, processing, and reviewing documents responsive to the six categories even prior to receiving the requests by the U.S. Department of Justice (“DOJ”).

To date, in addition to the over 40,000 pages that FDA previously produced to DOJ that were forwarded to Defendants, *see* Dkt. No. 67, at 3, FDA has collected over 19,000 documents<sup>1</sup> from more than 45 custodians located in 8 FDA offices, including the Office of

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<sup>1</sup> FDA previously stated that it had collected over 62,000 documents in response to the subpoena in the SEC matter, but then discovered that many of those documents were false hits containing the word “Holmes” but that were unrelated to Defendant Holmes or Theranos. New searches were run to exclude the false hits, which account for the new and lower number of potentially responsive documents.



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Legislation, the Office of Media Affairs, the Office of Regulatory Affairs, the Office of the Chief Counsel, and the following offices in FDA's Center for Devices and Radiological Health ("CDRH"): the Office of the Center Director; the Office of Communication and Education; the Office of Surveillance and Biometrics; and the Office of In Vitro Diagnostics and Radiological Health. Although FDA has no practicable electronic mechanism by which it can isolate the documents in its present collection that correspond to the six categories requested in the above-captioned action,<sup>2</sup> to the extent FDA can prioritize documents from custodians likely to have documents responsive to the six categories, it will do so. For example, FDA will prioritize documents from its Office of Media Affairs, which is the office most likely to have documents responsive to Category 1 of Defendants' motion to compel, which seeks all communications regarding Theranos between the government and the Wall Street Journal (see Dkt. No. 67).

FDA is committed to continue working cooperatively with the parties to provide them non-privileged documents responsive to the six requested categories in the most efficient manner possible. To that end, FDA will produce documents responsive to all six categories and is waiving its deliberative process privilege for Theranos-specific documents.<sup>3</sup>

FDA will continue to process the documents it has collected and will produce to the parties in the above-captioned matter all Theranos-related documents, including those responsive to the six categories requested in this matter, subject to the following limitations, which were discussed in greater detail in my June 7, 2019 letter to Mr. Bostic (Dkt. No. 79-4):

1. Most importantly, FDA is prohibited by law from producing to the parties in the above-captioned matter documents containing Theranos's trade secret and/or confidential commercial information without (1) a waiver from Theranos's assignee or (2) a court order directing FDA to produce Theranos's trade secret and confidential commercial information to the parties. *See 21 U.S.C. § 331(j); 21 U.S.C. § 360j(c); 18 U.S.C. § 1905; 21 C.F.R. § 20.61.* In the SEC matter, Theranos's assignee recently provided a waiver permitting FDA to produce Theranos's trade secret and confidential commercial information in response to the subpoena issued by Defendant Balwani and pursuant to the supplemental protective order entered

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<sup>2</sup> FDA does not currently have the capability to extract a narrower set of documents from its current collection and exclude those from further review for the SEC matter. In other words, were FDA to electronically isolate the documents in its collection that are potentially responsive to the six categories, FDA would have to review those documents a second time to respond to Defendant Balwani's subpoena in the SEC case. Accordingly, by proceeding with its processing, review, and production of its broader collection of Theranos-related documents, FDA is undertaking the most efficient route toward resolving the parties' requests in both related matters.

<sup>3</sup> FDA has not waived its deliberative process privilege for non-Theranos-specific documents related to the agency's non-final laboratory developed test ("LDT") policy and draft guidance, and deliberations regarding the same.



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in that case.<sup>4</sup> That waiver permits FDA to review documents more quickly because it no longer needs to review for, and redact, Theranos's trade secret and confidential commercial information.<sup>5</sup> Indeed, FDA expects to make a production of Theranos-related documents to Defendant Balwani's counsel this week in the SEC matter. That production will consist of over 350 documents and 5,500 pages. FDA can provide the parties in the above-referenced matter those documents as soon as it obtains a waiver from Theranos's assignee or a court order directing FDA to produce the documents that it produces to Defendant Balwani's counsel in the SEC matter to the parties in the above-captioned action. FDA estimates that it can complete its entire production of the documents it has collected in response to the subpoena in six months if there is a waiver from Theranos's assignee or a court order directing the agency to produce documents to the parties in the above-captioned action; that timeframe will be more than twice as long without a waiver or court order, because FDA will have to re-review the documents and redact Theranos's trade secret and commercial confidential information from them before they can be produced to the parties in the above-referenced matter.

2. FDA intends to redact third-party trade secret and confidential commercial information from the responsive documents as required under the law. 21 U.S.C. § 331(j); 21 U.S.C. § 360j(c); 18 U.S.C. § 1905; 21 C.F.R. § 20.61.
3. To the extent a document is privileged or otherwise protected (including but not limited to attorney-client communications and attorney work product, personal and private information, and information that could be used to identify a confidential informant, if any), FDA will redact it or, if it is not segregable, withhold it in its entirety, except that it will release the document or a segregable portion of it, as applicable, to the extent it is subject to FDA's deliberative process privilege waiver.
4. To the extent a document is available from public media or similar organizations (including but not limited to Bulletin Intelligence, GenomeWeb, The Gray Sheet, PharmaVOICE, POLITICO Pulse, and Google Alerts) and does not otherwise include commentary by FDA employees (such as, for example, an employee forwarding a news article and commenting on the article in the body of the email), FDA will not produce it, as such items are available to the parties by other, less burdensome means.
5. To the extent FDA identifies a document that it has already produced to DOJ and which DOJ has produced to the parties in the above-captioned action, FDA will not produce that document again. Of course, given the limitations of FDA's technology,

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<sup>4</sup> The waiver from Theranos's assignee in the SEC case followed multiple requests to Defendant Balwani's counsel and counsel to Theranos's assignee over several months and protracted negotiations regarding a protective order requested by the assignee.

<sup>5</sup> Of course, FDA still must review for, and redact, third-party trade secret and confidential commercial information. However, FDA expects that there will be little of that information among the collected documents.



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outlined in our June 7 letter, it is likely that the productions will include duplicates of previously-produced documents.

6. FDA will limit its search for responsive documents to the date range January 1, 2010 through June 30, 2018, which is the date range for which FDA collected documents pursuant to Defendant Balwani's subpoena in the SEC matter. Such timeframe is more than reasonable, as it encompasses the timeframe of the single allegation related to FDA in the Superseding Indictment (late 2013 through 2014), *see* Dkt. No. 39, at ¶ 12(F); it is the date range selected by Defendant Balwani in his subpoena for the SEC matter; and it reduces the undue burden on FDA that would result from the original, non-time-limited request.

To summarize, FDA is not withholding responsive documents based on a determination of relevance, and it is not withholding documents that relate specifically to Theranos on the basis of the deliberative process privilege. It does, however, need to review the collected documents for responsiveness as well as the other privileges and protections discussed above.

I trust that this letter conveys the information that the Court directed FDA to provide to the parties. FDA will continue to work as expeditiously as possible to provide the parties with the requested material, as set forth above.

Sincerely,

Marci B. Norton  
Senior Counsel